



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,225	01/21/2000	Lori L. Carrigan	PO4355USOPHI1244	5584

27310 7590 08/13/2002

PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

[REDACTED] EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
1638	15

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/489,225

Applicant(s)

CARRIGAN, LORI L.

Examiner

Ashwin Mehta

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 May 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-32 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Prosecution Application

1. The transmittal filed on 31 May 2002 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/489,225 is acceptable and a RCE has been established. An action on the RCE follows.
2. The rejection of claims 11, 15, 19, 24, 28, and 32 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious is replaced with the rejection under 102(3) and 103(a) below.

Specification

3. The specification is objected to for the inclusion of blank lines where ATCC accession numbers should be, for example on page 7, last paragraph.

Claim Objections

4. Claims 6, 12, 16, 25, and 29 are objected to for the following informalities: in line 1 of the claims, the article "A" should be --The--.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1638

5. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant traverses the rejection in the paper received 31 May 2002. Applicant's arguments were fully considered but were not found persuasive.

The recitation "38T27" in claims 1, 5, 7, 11, 15, 19, 24, 28, and 32 render the claims and those dependent thereon indefinite. Since the name "38T27" is not known in the art, the use of said name does not carry art recognized limitations as to the specific characteristics or essential characteristics which are associated with that denomination. The name "38T27" does not clearly identify the claimed hybrid maize seed, and does not set forth the metes and bounds of the claimed invention. In addition, the name appears to be arbitrary and the specific characteristics associated therewith could be modified, as there is no claimed description of the maize plant that encompasses all of its traits. Amending claims 1, 5, and 7 to recite the ATCC deposit number in which hybrid maize seed 38T27 has been deposited would overcome the rejection.

Applicants reiterate that they will refrain from depositing the lines until an indication of allowable subject matter has been issued (response, page 3, 2nd full paragraph). Applicants' intent is acknowledged. As all of the claims are not in condition for allowance, the rejection is maintained.

In claim 6: there is improper antecedent basis for "protoplasts" in line 1. It is suggested that the term be removed from the claim, and that a new claim be introduced directed towards protoplasts produced from the tissue culture of claim 5.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

Art Unit: 1638

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 8-19 and 21-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any maize plant or its parts wherein at least one ancestor is 38T27 and expresses a combination of at least two 38T27 traits; or a hybrid maize plant grown from seed of 38T27, or which has all the morphological and physiological traits as the plant grown from 38T27 seed, and which contains one or more transgenes; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more transgenes; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more transgenes and which expresses at least two 38T27 traits; or a hybrid maize plant grown from 38T27 seed wherein the genetic material contains one or more genes transferred by backcrossing; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more genes transferred by backcrossing; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more genes transferred by backcrossing and which expresses at least two 38T27 traits.

The specification describes morphological and physiological traits of a hybrid maize plant grown from hybrid maize seed arbitrarily designated “38T27”, which was produced by crossing two inbred lines designated “GE533329” and “GE501400” (page 7, last paragraph; page

Art Unit: 1638

15, last three paragraphs; Table 1, pages 16-18). The specification also describes comparisons of 38T27 to other hybrid plants (pages 19-32). The specification further indicates that upon allowance of any claims, all restrictions on the availability to a deposit of 2500 seeds of 38T27 with the American Type Culture Collection will be removed, that the deposit will be maintained without restriction, that all requirements of 37 CFR 1.801-1.809 will be met, and that the deposit will follow the requirements of 37 CFR 1.801-1.809 (page 46).

However, the specification does not describe 38T27 as being male sterile. The specification discusses how plants may be manipulated to be male sterile (paragraph bridging pages 2 and 3 and the first full paragraph of page 3). However, the morphological and physiological description of plant 38T27 in the specification does not indicate that it is male sterile. The following amendments are suggested: 1) in claims 8 and 21, replace “male sterile” with --detasseled--; 2) add a new claim 33 directed towards a method of producing a male sterile maize plant comprising transforming the maize plant of claim 2 with a nucleic acid molecule that confers male sterility, and a new claim 34 directed towards a male-sterile maize plant produced by the method of claim 33.

The specification also does not describe the plants developed by the maize breeding programs, transgenic 38T27 plants, 38T27 plants further comprising genes transferred by backcrossing, or maize plants wherein at least one ancestor is corn variety 38T27 and which express at least two of the traits listed in claims 11, 15, 19, 24, 28, or 32. The morphological and physiological traits of the corn plants that are crossed with 38T27, and with progeny of that cross, are unknown, and the description of progeny and descendants of corn plant 38T27 are unknown. The description of corn plant 38T27 is not indicative of any of its descendants. To

say that a plant expresses two traits of another plant is not sufficient information to describe that plant, as numerous corn plants express at least two of the same traits as those expressed by 38T27. Two plant traits do not provide any description of the other traits of a plant. It is possible that the claimed plants inherited the genes governing those traits from an ancestor other than plant 38T27. For example, Carbone Jr. (U. S. Patent No. 6,180,857) describes a corn plant designated "33P66," which expresses at least two traits that are also expressed by 38T27, such as the traits for yield potential and test weight (col. 12, lines 5-7). The instantly claimed corn plants could have 33P66 as an ancestor, as well as 38T27, in which case the yield potential and test weight traits, for example, could have been inherited from 33P66. Further, it is not known what genes of 38T27 would be affected in the claimed methods comprising breeding programs. The traits of the plants produced by, and which can be further used in, the programs are unknown and not described by the specification. The transgenes and genes introduced into 38T27 by backcrossing may be of gene(s) that effect any trait or more than one trait. Such plants would express different morphological and physiological traits from 38T27, and which are not described. It is suggested that claims 12 and 25 be amended to list the types of transgenes contemplated in the specification, for example disease or pest resistance genes, provided the prior art teaches those isolated genes. Given the breadth of the claims encompassing corn plants expressing at least two traits that are also expressed by 38T27, 38T27 that is also male sterile, any transgenic 38T27 plant, any 38T27 plant further having any gene(s) introduced by backcrossing, methods comprising the use of such plants, lack of guidance of the specification as discussed above, the specification fails to provide an adequate written description of the multitude of corn plants and their parts encompassed by the claims.

Art Unit: 1638

7. Claims 1-32 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants traverse the rejection in the paper received 31 May 2002. Applicant's arguments were fully considered but were not persuasive.

Since the seed claimed is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. It is noted that applicants intend to deposit seeds for 38T27 at the ATCC, but there is no indication that the seeds have been deposited. If the deposit of these seeds is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance

Art Unit: 1638

of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

Applicants indicate that the ATCC deposit will be delayed until an indication of allowable subject matter has been issued (response, page 3, 1st full paragraph). Applicant's intent is acknowledged. As the claims are not in condition for allowance, the rejection is maintained.

Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-32 are rejected under 35 U.S.C. § 102 (e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 (a) as obvious over Caralone, Jr. (U.S. Patent No. 6,180,857). Applicant traverses the rejection in the paper received 31 May 2002, as applied to claims 11, 15, 19, 24, 28, and 32. Applicant's arguments were fully considered but were not found persuasive.

The claims are broadly drawn towards hybrid maize seed designated "38T27"; a corn plant produced by growing seed of any hybrid maize seed designated 38T27, or parts thereof; or wherein said plant is male sterile; or any maize plant or its parts wherein at least one ancestor is 38T27 and expresses a combination of at least two 38T27 traits; or a hybrid maize plant grown from seed of 38T27, or which has all the morphological and physiological traits as the plant grown from 38T27 seed, and which contains one or more transgenes; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more transgenes; or any maize plant wherein at least one ancestor is the hybrid maize

plant comprising one or more transgenes and which expresses at least 2 38T27 traits; or a hybrid maize plant grown from 38T27 seed wherein the genetic material contains one or more genes transferred by backcrossing; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more genes transferred by backcrossing; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more genes transferred by backcrossing and which expresses at least 2 38T27 traits.

Carlone, Jr. teaches seed of a hybrid maize line designated "33P66," plants produced by growing said seed, and plants and plant parts, including pollen and ovules (col. 12, lines 5-18; Table 1; col. 15, line 45 to col. 16, line 55; Tables 2A-2B; col. 19, line 27 to col. 20, line 39; Tables 3-4; col. 21, lines 3-17; claims). It appears that the claimed plants and seeds of the instant invention may be the same as 33P66, given that they express common traits, such as the traits for yield potential and test weight (col. 12, lines 5-7). Alternatively, if the claimed plants, plant parts, and seeds of 38T27 are not identical to 33P66, then it appears that 33P66 only differs from the instantly claimed plants, plant parts, and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to 38T27. Carlone, Jr. also teaches a maize plant having all the morphological and physiological characteristics of 33P66 and being male sterile, and methods to confer male sterility to corn plants, and asserts that large-scale commercial maize hybrid production requires the use of some form of male sterility, and that a reliable method of controlling male fertility in plants also offers the opportunity for improved plant breeding (col. 1, line 53 to col. 2, line 60;

claims). Caralone, Jr. also teaches production of tissue culture of regenerable cells from a plant of line 33P66, wherein regenerable cells are from tissues including flowers, pollen, ovules, among others; a plant produced from tissue culture of 33P66 that is capable of expressing all of the morphological and physiological traits of 33P66; corn plant breeding programs, including backcrossing, pedigree breeding, recurrent selection, among others; maize plants having as at least one ancestor 33P66, or 33P66 containing one or more transgenes, or 33P66 containing one or more genes transferred by backcrossing; use of backcrossing to introduce gene(s) for desirable traits; 33P66 comprising at least one transgene, and using the plant in maize breeding programs; maize plants produced by those breeding programs, 33P66 comprising genes(s) introduced by backcrossing, and use of the plant in a method for developing a plant for breeding programs (col. 2, line 61 to col. 5, line 60; col. 21, line 43 to col. 31, line 17; claims). The claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by Caralone, Jr.

Applicant argues that the claims recite specific traits only to the extent that they are “38T27” traits, thereby coming solely from 38T27 seed/germplasm. Applicants argue that the claims also recite that the claimed plant must have 38T27 as an ancestor. Applicants argue that one can tell from breeding history if the claimed plant has 38T27 as an ancestor, and that its unique genetic background will result in the claimed plant (response, paragraph bridging pages 4-5). However, the claimed plants can also have as parents other corn plants that also express the listed traits, and can inherit the unique genetic profile governing the traits from that parent. The specification does not teach how or why the genetic profile of 38T27, which governs the traits enumerated in the claims, differs from that of other plants, such as 33P66, that also express

any of these traits. Applicants attempt to distinguish a “38T27 trait” from the same trait in another plant by claiming that a different genetic profile gave rise to it. However no information is given that would allow one to compare the genetic profile giving rise to a trait in 38T27 versus other plants. One can only rely on the observation of the trait itself, which does not distinguish the genes governing it as belonging only to 38T27 versus 33P66. Calling a trait a “38T27 trait” then does not distinguish the same trait as it appears in other plants. Applicants have not provided the information necessary to determine if any of the traits enumerated in the claims came from 38T27 or another plant in the breeding history.

Applicant also argues that there is not teaching of dominance or heritability of traits, without which it cannot be said that there is an expectation of success that the combination of plants would achieve the combination enumerated in the claimed invention (response, page 5, 1st full paragraph). However, the plants claimed by Caralone, Jr. already express at least 2 of the traits enumerated in the instant claims. Further, Caralone, Jr. does teach using the disclosed plant to make further crosses. Applicant does not provide any evidence that the genes of the plants of Caralone, Jr. are not heritable. Further, Applicants do not provide any data on the dominance or heritability of the traits of the instantly claimed plants. Applicant also argues that it is not the phenotypic characteristics alone that are claimed, but the combination of physiological and morphological characteristics (response, page 5, 1st full paragraph). However, Applicants results do not show that the genes or alleles governing the test weight trait of 38T27, for example, are different from those governing that trait in 33P66.

9. No claims are allowed.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

August 8, 2002



ASHWIN D. MEHTA, PH.D
PATENT EXAMINER